TRANSLATION

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Form PCT/IPEA/416
GRA3144PCT		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/EP2004/014148	13.12.2004	12.12.2003

International Patent Classification (IPC) or national classification and IPC

A61K9/70

Applicant

LTS LOHMANN THERAPIE-SYSTEME AG

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

3. This report is also accompanied by ANNEXES, comprising:

   a. ☐ *(sent to the applicant and to the International Bureau)* a total of _____ sheets, as follows:

      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).

      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s))

      _____ , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
Name and mailing address of the IPEA/EP	Authorized officer
Facsimile No.	Telephone No.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/EP2004/014148

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on translations from the original language into the following language _____, which is the language of a translation furnished for the purposes of:

☐ international search (Rule 12.3 and 23.1(b))

☐ publication of the international application (Rule 12.4)

☐ international preliminary examination (Rule 55.2 and/or 55.3)

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☐ the international application as originally filed/furnished

☒ the description:

pages 1-11 as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☒ the claims:

nos. _____ as originally filed/furnished

nos.* _____ as amended (together with any statement) under Article 19

nos.* 1-12 received by this Authority on 17.09.2005 with letter of 15.09.2005

nos.* _____ received by this Authority on _____

☒ the drawings:

sheets 1/1 as originally filed/furnished

sheets* _____ received by this Authority on _____

sheets* _____ received by this Authority on _____

☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing *(specify)*: _____

☐ any table(s) related to sequence listing *(specify)*: _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages _____

☐ the claims, nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing *(specify)*: _____

☐ any table(s) related to sequence listing *(specify)*: _____

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/EP2004/014148

Box No. V **Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims		YES
	Claims	1-13	NO
Inventive step (IS)	Claims		YES
	Claims	1-13	NO
Industrial applicability (IA)	Claims	1-13	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

1. Cited documents

This report makes reference to the following documents:

D1: US 2002/142036 A1 (RUPPRECHT HERBERT ET AL) 3 October 2002 (2002-10-03)

D2: US-A-5 120 544 (HENLEY ET AL) 9 June 1992 (1992-06-09)

D3: US-A-5 906 814 (EPSTEIN ET AL) 25 May 1999 (1999-05-25)

D4: ABLETSHAUSER C B ET AL: "HERSTELLUNG UND UNTERSUCHUNG VON ISOLIERTEN MHPC-TANNIN-FILMEN PREPARATION AND INVESTIGATION OF ISOLATED MHPC-TANNIN FILMS" PHARMAZIE, DIE, PHARMAZEUTISCHER VERL., ESCHBORN, DE, vol. 47, no. 11, 1992, pages 870-871, XP001205680 ISSN: 0031-7144

2. Parameter (PCT Article 6)

Independent claim 1 discloses a pharmaceutical administration form that is defined by means of its tear resistance.

This claim is not clear and fails to meet the requirements of PCT Article 6 to the extent that the subject matter for which protection is sought is not clearly defined. The parameter 'tear resistance' does not allow a person skilled in the art to determine what the product is composed of. Furthermore, it is impossible to compare this parameter with the prior art.
The characterization of a product mainly by means of its parameters should be allowable only if the invention cannot be sufficiently defined in any other way.
In the present case, this type of formulation is, however, not allowable because it appears possible to describe the subject matter of the application in more concrete terms.

3. Novelty (PCT Article 33(2))

On the basis of the aforementioned objection with regard to clarity, the parameter 'tear resistance' was not taken into account during the course of further proceedings.

D1 (see example 4 on page 6) discloses a multilayered film as a transmucosal pharmaceutical form of film-forming polymers having a cover layer, at least one active substance-containing layer (for example, lidocaine, see page 3, column 1, line 42) and an adhesive layer, characterized in that the cover layer and/or the active

substance-containing layer consists of in situ crosslinked hydrophilic polymers. The subject matter of claims 1 to 13 is therefore not regarded as novel (EPC Article 54(1) and (2)).

D2 (see column 3, table 1 and claims) discloses crosslinked hydrogels for topical application containing lidocaine HCl. The subject matter of claims 1 to 3 and 5 to 10 is therefore not regarded as novel (EPC Article 54(1) and (2)).

D3 (see column 3, gel C in table 1 and claims) discloses a topical film-forming preparation containing: a) ethyl alcohol as a volatile solvent (80% w/w), b) a cellulose material (HPC, 1.8% w/w)), c) acetylsalycylic acid, d) glycerol monolaurate as a crosslinker and d) tetracaine (1% w/w) as an active substance. Lidocaine is an additional, preferred pain reliever. The subject matter of claims of claims 1 to 7 and 9 is therefore not regarded as novel (EPC Article 54(1) and (2)).

The subject matter of claims 1 to 13 is therefore not regarded as novel (EPC Article 54(1) and (2)).

4. Inventive step (PCT Article 33(3))

Since the subject matter of claims 1 to 13 is not novel, it also does not involve an inventive step (PCT Article 33(3)).

Box No. V — Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

5. Industrial applicability (PCT Article 33(4))

The subject matter of claims 1 to 13 meets the requirements of PCT Article 33(4) for industrial applicability.

6. Various comments

The phrase "characterized in that" ("it has a tear resistance ...") should be added to claim 1.

Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**

Continuation of: BOX I

Claims 1 to 12 meet the requirements of PCT Article 34(2)(b) because the subject matter of these claims does not go beyond the content of the application in the originally submitted version.